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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/727,282      | 11/30/2000  | Paul C. Dicesare     | P-4370              | 6293             |

26253 7590 04/10/2002

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EXAMINER

QUAN, ELIZABETH S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1743

DATE MAILED: 04/10/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/727,282

Applicant(s)

DICESARE ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 is dependent on claim 11, which already recites “wherein said ballast is substantially tubular and is securely engaged around portions of bellows adjacent the lower end of said bellows.”

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is rendered indefinite with a “ballast...having a density greater than said density of said liquid phase of said fluid sample” and “float having a density less than said density of said formed phase of said fluid sample and less than said density of said formed phase of said fluid sample.” The liquid phase, formed phase, fluid sample, and densities of the ballast, float, liquid phase, and formed phase have not been positively recited as elements. What is the liquid phase the ballast is compared to? What is the formed phase the float is compared to? Does the ballast have a density greater than water, oil, blood, milk, etc.? Does the float have a density less than water, oil, blood, milk, etc.? The claim can be amended by quantifying the density and

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including appropriate units. Additionally, “float having a density less than said density of said formed phase of said fluid sample and less than said density of said formed phase of said fluid sample” is redundant by twice reciting “density less than said density of said formed phase of said fluid sample.”

4. Claim 10 is rendered indefinite with a “ballast having a density greater than said density of said liquid phase of said blood” and “float having a density less than said density of said liquid phase of said blood and less than said density of said formed phase of said blood.” The liquid phase, formed phase, blood, and densities of the ballast, float, liquid phase, and formed phase have not been positively recited as elements. What is the liquid phase of blood the ballast is compared to? What is the formed phase of blood the float is compared to? Does the ballast have a density greater than the plasma, serum, etc. of blood? Does the float have a density less than the plasma, serum, etc. of blood? The claim can be amended by quantifying the density and including appropriate units. Additionally, “float having a density less than said density of said liquid phase of said blood and less than said density of said formed phase of said blood” is confusing and redundant.

5. Claims 2-6, 8, 9, 11, 14, and 15 are rejected based upon their dependency on rejected base claims.

***Claim Rejections - 35 USC § 102***

6. Claims 1-15 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/454,988 which has two common inventors with the instant application.

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Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application. Both applications disclose inventions with the same elements in the claims and specification. The FIELD OF THE INVENTION, DESCRIPTION OF RELATED ART, and SUMMARY OF THE INVENTION on Pages 2-16 of Application No. 09/454,988 are similar and directly relevant to corresponding sections of the specification in the instant application. The first embodiment as depicted in FIGS. 1-6 and the second embodiment as depicted in FIGS. 7-13 anticipate the claims in the instant application. The second embodiment discloses an invention identical to that in the instant application. Additionally, FIGS. 8-13 of Application No. 09/454,988 show the invention of the instant application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

### ***Double Patenting***

7. Applicant is advised that should claim 4 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-5, 7, 8, 10-12, 14, and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, and 14-17 of copending Application No. 09/454,988. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same elements in the same structural relationship. While the tubular shape of the ballast as claimed in claims 4, 5, 11 and 12 in the instant application has not been positively recited in the allowed claims of Application No. 09/454,988, it would have been obvious to use a tubular ballast to conform to the shape of the tubular container for easier axial migration of the separator. Applying the decision of *In re Dailey*, the configuration of the ballast is deemed a matter of choice to a person of ordinary skill in the absence of persuasive evidence that it is significant in solving a problem or is for any purpose.

10. Claims 6 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, and 14-17 of

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compending Application No. 09/454,988 in view of U.S. Patent No. 6,085,944 to Lang et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same elements in the same structural relationship except for a float with an annular groove engageable with an inwardly directed annular bead of the bellows.

This is a provisional obviousness-type double patenting rejection.

While the allowed claims of Application No. 09/454,988 recite a central passageway extending through the bellows, they do not recite a float with an annular groove engageable with an inwardly directed annular bead of the bellows as claimed in claims 6 and 13 in the instant application. However, Lang et al. disclose a syringe with a piston-cylinder unit comprising a retainer ring (34) positively locking with the cylinder liner (28) via fitting the circumferential annular bead (78) on the outside mantle of the retainer ring (34) into the circumferential annular groove (76) on the inside mantle of the cylinder liner (28) (see FIGS. 4 and 5; COL. 2, lines 49-56). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the annular bead of Lang et al. on the bellows of '988 and the annular groove of Lang et al. on the float of '988 for positively locking the two elements of the separator.

11. Claim 9 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, and 14-17 of compending Application No. 09/454,988 in view of U.S. Patent No. 4,083,788 to Ferrara. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same elements in the same structural relationship except for a plurality of resiliently deflectable arc sections and corresponding grooves.

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This is a provisional obviousness-type double patenting rejection.

While '988 recites a bellow member with initially conically convex top wall at the top for mounting, the application does not disclose a plurality of resiliently deflectable arc sections and corresponding grooves as claimed in claim 9. However, Ferrara discloses a blood serum separation unit comprising a stopper-plug (15) with slit (18) forming legs (19a,19b) and disk (14) typically with guiding legs (17a,17b,17c) (see FIGS. 1-7; COL. 4, lines 61-68; COL. 5, lines 1-33). While Ferrara discloses the legs of the disk prevent accidental wedging and twisting of the disk within the tube, it also appears the legs are for releasably mating the disk to the stopper-plug. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include resiliently deflectable arc sections and corresponding grooves as in Ferrara to releasably mate the disk to the stopper-plug and prevent accidental wedging and twisting of the disk within the tube.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The enclosed prior art includes one or more limitations recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the




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organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1193.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq  
April 8, 2002

  
Jill Warden  
Supervisory Patent Examiner  
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